INDEX

Volume 31 1976

A

The *Abbott Laboratories* Decision
The New Age of FDA Rule-Making. July, p. 393.

Abbreviated New Drug Applications
Changing Regulatory Patterns: New Device Legislation. Apr., p. 204.
Drug Law—Regulatory Developments. Apr., p. 211.

Adequate Scientific Evidence
Changing Regulatory Patterns: New Device Legislation. Apr., p. 204.

Administrative Procedure Act
The New Age of FDA Rule-Making. July, p. 393.

Adulteration
Cosmetic Quality Assurance—Alias Cosmetic Good Manufacturing Practices. Mar., p. 167.
Dotterweich Revisited — Criminal Liability Under the Federal Food, Drug and Cosmetic Act. Feb., p. 69.
How to Export Fishery Products to the United States. May, p. 289.
The Philosophy of Enforcement. June, p. 324.
The Role of the Department of Justice in Enforcing the Federal Food, Drug and Cosmetic Act. June, p. 333.

Advertising
The Network of Consumer Information. Dec., p. 664.
Regulatory Survival Kit. Apr., p. 241.
Special Problems in Advertising. May, p. 252.

Advertising of Drugs
The FTC's Proposed Rule on OTC Drug Advertising. Mar., p. 147.

Advisory Panels
The FDA's OTC Review—The Light at the End of the Tunnel. Mar., p. 141.

Aerosol Cosmetics
Cosmetic Law—Pending Litigation. Apr., p. 198.

Alfaro, Julio E. and Zimmerman, Julius G.—The Food Law of Argentina. Oct., p. 545.

Allergens
Cosmetic Ingredient Labeling—An FDA Chimera. Feb., p. 109.

Allowable Daily Intake
NAS-NRC GRAS List Survey (Phase III) — Incentives for Further Industry Cooperation and Participation. Mar., p. 132.

Alternatives to Peril. Sept., p. 497.

Anderson, Robert N.—An Overview of Recent Regulatory Developments —The Case for Evidentiary Hearings. Mar., p. 159.

Animal Drugs
The Food Law of Argentina. Oct., p. 545.
A Response to New Approaches to Be Used in the Regulation of Animal Drugs. Jan., p. 59.

Animal Feed
FDA With a Capital "L". Dec., p. 649.
The Food Law of Argentina. Oct., p. 545.
An Overview of Recent Regulatory Developments—Veterinary Medicine. Mar., p. 153.
Status of the FDA's Program on the Use of Antibiotics in Animal Feeds. Jan., p. 54.

Antibiotics
FDA With a Capital "L". Dec., p. 649.

Alcoholic Beverages
FDA With a Capital "L". Dec., p. 649.

Appendix
Food Law—International. Apr., p. 218.
Nutrition Regulations in Product Development. Apr., p. 232.

An Approach to Toxiocological Evaluation. Dec., p. 640.

Apse, Jan—Current Topics in Canadian Drug Regulatory Affairs. Jan., p. 11.

Are Food Additives Overregulated? Nov., p. 627.

Argentine Food Law
The Food Law of Argentina. Oct., p. 545.

B

Balanced Government Regulation of Consumer Products. Nov., p. 592.

Barnum, H. J.—The Network of Consumer Information. Dec., p. 664.

Bauman, Howard E.—Nutrition Regulations in Product Development. Apr., p. 232.

Beers, William O.—Wanted—Plain Talk About Additives. Aug., p. 448.

Berdick, Murray—Cosmetic Ingredient Labeling—The Nomenclature Problem. Feb., p. 125.

Bio-Research Monitoring Program
FDA With a Capital "L". Dec., p. 649.

Bioavailability Standards
The Role of the Compendia in Establishing Drug Standards. May, p. 276.

Bioequivalence/Bioavailability
FDA With a Capital "L". Dec., p. 649.

Bioequivalence/Bioavailability—The Basic Legal and Philosophical Issues. Jan., p. 46.

Bioequivalence/Bioavailability — The FDA's Plans. Jan., p. 32.

Bioequivalance/Bioavailability—A Manufacturer's View. Jan., p. 39.

Blake, Martin I.—The Role of the Compendia in Establishing Drug Standards. May, p. 276.

Breach of Warranty
Product Liability—1975. Mar., p. 175.

Bromatological Code
The Food Law of Argentina. Oct., p. 545.

Bromatopeia
The Food Law of Argentina. Oct., p. 545.

Brooker, J. R.—How to Export Fishery Products to the United States. May, p. 289.

Burditt, George M.—The *Park* Case in Perspective. Mar., p. 137.

Byerley, Walter E.—Cosmetic Ingredient Labeling—An FDA Chimera. Feb., p. 109.

C

"CT" Scanner
FDA With a Capital "L". Dec., p. 649.

Canadian Regulation of Drugs
Current Topics in Canadian Drug Regulatory Affairs. Jan., p. 11.

Cancerophobia
Alternatives to Peril. Sept., p. 497.

Carcinogenicity Potential of Red No. 2
Recent Developments Under FOIA and FACA Directly Affecting the Pharmaceutical Industry. Sept., p. 507.

Carcinogens
Alternatives to Peril. Sept., p. 497.
Toxicology—The Exact Use of an Inexact Science. Aug., p. 455.

Cavallito, C. J.—Bioequivalence/Bioavailability—A Manufacturer's View. Jan., p. 39.

Changing Regulatory Patterns: New Device Legislation. Apr., p. 204.

Codex Alimentarius
Food Law—International. Apr., p. 218.

Coleman, Terry.—The Use of Regulations to Enforce Statutory Quality Assurance Requirements. Feb., p. 96.

Color Additives
FDA—Social Trend and Regulatory Reform. Nov., p. 605.
FDA With a Capital "L". Dec., p. 649.

Coloring Agents
The Food Law of Argentina. Oct., p. 545.

Commodity Identification
The Food Law of Argentina. Oct., p. 545.

Condon, William J.—Product Liability —1975. Mar., p. 175.

Consumer Interests—Do We Get the Foods We Want? Dec., p. 656.

Consumer Protection
Food Law—International. Apr., p. 218.

Consumer Safety Administration
FDA With a Capital "L". Dec., p. 649.

Consumers
The Philosophy of Enforcement. June, p. 324.

Contact Lenses
Changing Regulatory Patterns: New Device Legislation. Apr., p. 204.

"Contingency" Import Registrations
Legal Developments Relating to Controlled Drugs. Aug., p. 465.

Controlled Substances Act
Legal Developments Relating to Controlled Drugs. Aug., p. 465.

Corporate Strategy
Management of Scientific Resources. July, p. 413.

Cosmetic Good Manufacturing Practices
Cosmetic Quality Assurance—Alias Cosmetic Good Manufacturing Practices. Mar., p. 167.
Quality Assurance Procedures for the Cosmetics Industry — The FDA's Viewpoint. Feb., p. 101.
The Use of Regulations to Enforce Statutory Quality Assurance Requirements. Feb., p. 96.

Cosmetic Ingredient Labeling
Cosmetic Law—Pending Litigation. Apr., p. 198.
Status Report on Cosmetic Ingredient Labeling. Feb., p. 121.

Cosmetic Ingredient Labeling—An FDA Chimera. Feb., p. 109.

Cosmetic Ingredient Labeling—The Nomenclature Problem. Feb., p. 125.

Cosmetic Ingredient Labeling Requirements. Feb., p. 115.

Cosmetic Ingredient Review Program
Recent Developments Under FOIA and FACA Directly Affecting the Pharmaceutical Industry. Sept., p. 507.

Cosmetic Law—Pending Litigation. Apr., p. 198.

Cosmetic Quality Assurance—Alias Cosmetic Good Manufacturing Practices. Mar., p. 167.

Cosmetics
Quality Assurance Guidelines—The Industry's Viewpoint. Feb., p. 106.

The Cost Effectiveness of Medical Device Standards. Feb., p. 81.

Current Topics in Canadian Drug Regulatory Affairs. Jan., p. 11.

Cyclamate
FDA With a Capital "L". Dec., p. 649.
Food Regulation: Quo Vadis? Apr., p. 188.

D

DES
FDA With a Capital "L". Dec., p. 649.

Delaney Clause
FDA—Social Trend and Regulatory Reform. Nov., p. 605.

Dextra Sugar
Food Regulation: Quo Vadis? Apr., p. 188.

Dietary Supplements
Nutrition Regulations in Product Development. Apr., p. 232.

Dissolution Testing
The Role of the Compendia in Establishing Drug Standards. May, p. 276.

The *Dotterweich* Doctrine
Enforcement Trends Under the Federal Food, Drug and Cosmetic Act—A View from Outside. June, p. 338.
The *Park* Case in Perspective. Mar., p. 137.
Section 305 Hearings—Defense Considerations. July, p. 386.
A Violation of the Federal Food, Drug and Cosmetic Act—A Crime in Search of a Criminal. Nov., p. 616.

Dotterweich Revisited—Criminal Liability Under the Federal Food, Drug and Cosmetic Act. Feb., p. 69.

Drug Classifications
Legal Considerations in Establishing Third and Fourth Classes of Drug Products. Jan., p. 4.

Drug Efficacy Study Implementation
Bioequivalence/Bioavailability — The Basic Legal and Philosophical Issues. Jan., p. 46.
Changing Regulatory Patterns: New Device Legislation. Apr., p. 204.
Drug Law—Regulatory Developments. Apr., p. 211.
A Violation of the Federal Food, Drug and Cosmetic Act—A Crime in Search of a Criminal. Nov., p. 616.

Drug Information
FDA—Social Trend and Regulatory Reform. Nov., p. 605.

Drug Lag
FDA—Social Trend and Regulatory Reform. Nov., p. 605.

Drug Law—Regulatory Developments. Apr., p. 211.

Drug Standardization
The Role of the Compendia in Establishing Drug Standards. May, p. 276.

Due Process
Legal Implications of Good Manufacturing Practice Regulations. Aug., p. 473.

E

Eiermann, Heinz J.—Cosmetic Ingredient Labeling Requirements. Feb., p. 115.

Enforcement Trends Under the Federal Food, Drug and Cosmetic Act—A View from Outside. June, p. 338.

Estrogenic Drugs
FDA With a Capital "L". Dec., p. 649.

European Food Law Association
Food Law—International. Apr., p. 218.

Evidentiary Hearings
An Overview of Recent Regulatory Developments—The Case for Evidentiary Hearings. Mar., p. 159.

Evolving Approaches to the Regulation of Prescription Drugs. Sept., p. 521.

Expert Panels
Changing Regulatory Patterns: New Device Legislation. Apr., p. 204.

F

FDA Authority Over Drugs
The New Age of FDA Rule-Making. July, p. 393.

FDA Labeling Rule
Special Problems in Advertising. May, p. 252.

FDA—Social Trend and Regulatory Reform. Nov., p. 605.

FDA With a Capital "L". Dec., p. 649.

FDA-NCI Review Group
FDA With a Capital "L". Dec., p. 649.

The FDA's OTC Review—The Light at the End of the Tunnel. Mar., p. 141.

FDA's Seizure Procedures
The Philosophy of Enforcement. June, p. 324.

The FTC's Proposed Rule on OTC Drug Advertising. Mar., p. 147.

Failure-to-Warn Cases
Product Liability—1975. Mar., p. 175.

Farquhar, John W.—The Role of Microbiology in the Integrity of Foods. Jan., p. 17.

Fine, Sam D.—The Philosophy of Enforcement. June, p. 324.

Fink, Joseph L. and Myers, Maven J. Legal Considerations in Establishing Third and Fourth Classes of Drug Products. Jan., p. 4.

Fluorocarbon-vs.-the-Ozone Policy
FDA With a Capital "L". Dec., p. 649.

Food Additives
Are Food Additives Overregulated? Nov., p. 627.
Consumer Interests—Do We Get the Foods We Want? Dec., p. 656.
Food Additives—A Study in the Evolution of Safety. July, p. 404.
Food Law—International. Apr., p. 218.
The Food Law of Argentina. Oct., p. 545.
How to Export Fishery Products to the United States. May, p. 289.
NAS-NRC GRAS List Survey (Phase III) — Incentives for Further Industry Cooperation and Participation. Mar., p. 132.
Review of the 1970 NAS GRAS Pilot Survey (Phase I) and the 1971 NAS Comprehensive Survey (Phase II). Jan., p. 26.
Toxicology—The Exact Use of an Inexact Science. Aug., p. 455.
Wanted—Plain Talk About Additives. Aug., p. 448.

Food Additives—A Study in the Evolution of Safety. July, p. 404.

Food Additives Amendments
Regulatory Aspects of Food Additives—Yesterday, Today and Tomorrow. May, p. 264.

Food and Agricultural Organization
Food Law—International. Apr., p. 218.

Food Faddists
Wanted—Plain Talk About Additives. Aug., p. 448.

Food Labeling
Food Law—International. Apr., p. 218.

Food Law—International. Apr., p. 218.

The Food Law of Argentina. Oct., p. 545.

Food Law Research Centre
Food Law—International. Apr., p. 218.

Food, Nutritional Labeling
Nutrition Regulations in Product Development. Apr., p. 232.

Food Regulation: Quo Vadis? Apr., p. 188.

Form FD-466
Section 305 Hearings—Defense Considerations. July, p. 386.

Freedom of Information Regulations
FDA With a Capital "L". Dec., p. 649.

Freedom of Information Statements
An Overview of Recent Regulatory Developments—Veterinary Medicine. Mar., p. 153.

Frozen Foods
The Role of Microbiology in the Integrity of Foods. Jan., p. 17.

G

GRAS Review
An Approach to Toxicological Evaluation. Dec., p. 640.
FDA With a Capital "L". Dec., p. 649.

GRAS Substances
Are Food Additives Overregulated? Nov., p. 627.
Food Additives—A Study in the Evolution of Safety. July, p. 404.
NAS-NRC GRAS List Survey (Phase III) — Incentives for Further Industry Cooperation and Participation. Mar., p. 132.

Regulatory Aspects of Food Additives—Yesterday, Today and Tomorrow. May, p. 264.
Review of the 1970 NAS GRAS Pilot Survey (Phase I) and the 1971 NAS Comprehensive Survey (Phase II). Jan., p. 26.
Toxicology—The Exact Use of an Inexact Science. Aug., p. 455.
Wanted—Plain Talk About Additives. Aug., p. 448.

Gardner, Sherwin—An Approach to Toxicological Evaluation. Dec., p. 640.

Geller, Jay H.—The Medical Device Amendments of 1976—Major Features and Comparisons. Aug., p. 424.

Gibbons, Patrick V.—Legal Implications of Good Manufacturing Practice Regulations. Aug., p. 473.

Gilhooley, Margaret—Status Report on Cosmetic Ingredient Labeling. Feb., p. 121.

Goldenfield, I. H.—Regulatory Survival Kit. Apr., p. 241.

Good Laboratory Practices
An Approach to Toxicological Evaluation. Dec., p. 640.
Are Food Additives Overregulated? Nov., p. 627.
Food Additives—A Study in the Evolution of Safety. July, p. 404.

Good Laboratory Practices Regulations
FDA With a Capital "L". Dec., p. 649.

Good Manufacturing Practice Regulations
The Medical Device Amendments of 1976—Major Features and Comparisons. Aug., p. 424.

Good Manufacturing Practices
Are Food Additives Overregulated? Nov., p. 627.
Changing Regulatory Patterns: New Device Legislation. Apr., p. 204.
Drug Law—Regulatory Developments. Apr., p. 211.
FDA—Social Trend and Regulatory Reform. Nov., p. 605.
FDA With a Capital "L". Dec., p. 649.
Food Regulation: Quo Vadis? Apr., p. 188.
Handling FDA Injunction Actions. June, p. 366.
How to Export Fishery Products to the United States. May, p. 289.
Legal Implications of Good Manufacturing Practice Regulations. Aug., p. 473.
Quality Assurance Procedures for the Cosmetics Industry—The FDA's Viewpoint. Feb., p. 101.
Regulatory Aspects of Food Additives—Yesterday, Today and Tomorrow. May, p. 264.
The Role of Microbiology in the Integrity of Foods. Jan., p. 17.
The Use of Regulations to Enforce Statutory Quality Assurance Requirements. Feb., p. 96.
A Violation of the Federal Food, Drug and Cosmetic Act—A Crime in Search of a Criminal. Nov., p. 616.

Graham, Dee M.—Review of the 1970 NAS GRAS Pilot Survey (Phase I) and the 1971 NAS Comprehensive Survey (Phase II). Jan., p. 26.

Grossmann, Stanley M.—Cosmetic Law—Pending Litigation. Apr., p. 198.

Guest, Gerald B.—Status of the FDA's Program on the Use of Antibiotics in Animal Feeds. Jan., p. 54.

H

Handling FDA Injunction Actions. June, p. 366.

Harkins, Robert W.
NAS-NRC GRAS List Survey (Phase III)—Incentives for Further Industry Cooperation and Participation. Mar., p. 132.
Product Recall. July, p. 383.

The *Y. Hata* Decision
A Violation of the Federal Food, Drug and Cosmetic Act—A Crime in Search of a Criminal. Nov., p. 616.

Henteleff, Thomas O.—Legal Developments Relating to Controlled Drugs. Aug., p. 465.

Herzog, Richard B.—The FTC's Proposed Rule on OTC Drug Advertising. Mar., p. 147.

Hoffman, Joel E.—Enforcement Trends Under the Federal Food, Drug and Cosmetic Act—A View from Outside. June, p. 338.
Well-Controlled Investigations and Medical Devices. Feb., p. 86.

How to Comply With the New Medical Device Law. June, p. 312.

How to Export Fishery Products to the United States. May, p. 289.

Hutt, Peter Barton—Balanced Government Regulation of Consumer Products. Nov., p. 592.

Hypoallergenic
Cosmetic Law—Pending Litigation. Apr., p. 198.
FDA With a Capital "L". Dec., p. 649.

I

***In Vitro* Reagents**
The Medical Device Amendments of 1976—Major Features and Comparisons. Aug., p. 424.

***In Vitro* Testing**
Bioequivalence/Bioavailability — The FDA's Plans. Jan., p. 32.
Bioequivalence/Bioavailability—A Manufacturer's View. Jan., p. 39.
Well-Controlled Investigations Under the Medical Device Amendments of 1976. Sept., p. 485.

***In Vivo* Performance**
Bioequivalence/Bioavailability — The FDA's Plans. Jan., p. 32.

***In Vivo* Testing**
Well-Controlled Investigations Under the Medical Device Amendments of 1976. Sept., p. 485.

Ingredient Labeling
FDA With a Capital "L". Dec., p. 649.
Wanted—Plain Talk About Additives. Aug., p. 448.

Ingredients
FDA—Social Trend and Regulatory Reform. Nov., p. 605.

Inter-American Bar Association
Food Law—International. Apr., p. 218.

International Harmonization
Food Law—International. Apr., p. 218.
The Food Law of Argentina. Oct., p. 545.

International Medication Systems
Handling FDA Injunction Actions. June, p. 366.

Interstate Commerce
The Medical Device Amendments of 1976—Major Features and Comparisons. Aug., p. 424.

Investigational New Drug
Recent Developments Under FOIA and FACA Directly Affecting the Pharmaceutical Industry. Sept., p. 507.
The Role of the Compendia in Establishing Drug Standards. May, p. 276.

Isley, C. Willard and O'Keefe, Daniel F.—*Dotterweich* Revisited—Criminal Liability Under the Federal Food, Drug and Cosmetic Act. Feb., p. 69.

J

Joint FAO/WHO Codex Alimentarius Commission
Food Law—International. Apr., p. 218.
The Food Law of Argentina. Oct., p. 545.

K

Kirschman, John C.—Toxicology—The Exact Use of an Inexact Science. Aug., p. 455.

L

Labeling
FDA—Social Trend and Regulatory Reform. Nov., p. 605.
FDA With a Capital "L". Dec., p. 649.

The Food Law of Argentina. Oct., p. 545.
New Regulatory Concepts in Rx Labeling for Patients. Sept., p. 531.

Labeling Requirements
How to Export Fishery Products to the United States. May, p. 289.

Laetrile
FDA With a Capital "L". Dec., p. 649.

Lambert, Eugene I.—Recalls, Regulatory Letters and Publicity—Quasi-Statutory Remedies. June, p. 360.

Land, Stuart J.—Bioequivalence/Bioavailability—The Basic Legal and Philosophical Issues. Jan., p. 46.

Law on Wines
The Food Law of Argentina. Oct., p. 545.

Law 13012
The Food Law of Argentina. Oct., p. 545.

Legal Considerations in Establishing Third and Fourth Classes of Drug Products. Jan., p. 4.

Legal Developments Relating to Controlled Drugs. Aug., p. 465.

Legal Implications of Good Manufacturing Practice Regulations. Aug., p. 473.

Litigation
The Role of the Department of Justice in Enforcing the Federal Food, Drug and Cosmetic Act. June, p. 333.

M

Management of Scientific Resources. July, p. 413.

Mandatory Injunction
Handling FDA Injunction Actions. June, p. 366.

Marketing Responsibility
Regulatory Survival Kit. Apr., p. 241.

McConachie, Charles R.—The Role of the Department of Justice in Enforcing the Federal Food, Drug and Cosmetic Act. June, p. 333.

McMurray, Raymond D. — Section 305 Hearings—Defense Considerations. July, p. 386.

McNamara, Stephen Hull—The New Age of FDA Rule-Making, July, p. 396.

Medical Device Amendments
Changing Regulatory Patterns: New Device Legislation. Apr., p. 204.
How to Comply with the New Medical Device Law. June, p. 312.
A Violation of the Federal Food, Drug and Cosmetic Act—A Crime in Search of a Criminal. Nov., p. 616.

The Medical Device Amendments of 1976—Major Features and Comparisons. Aug., p. 424.

Medical Devices
The Cost Effectiveness of Medical Device Standards. Feb., p. 81.
The Medical Device Amendments of 1976—Major Features and Comparisons. Aug., p. 424.
Well-Controlled Investigations and Medical Devices. Feb., p. 86.
Well-Controlled Investigations Under the Medical Device Amendments of 1976. Sept., p. 485.

Medical Devices Law
FDA With a Capital "L". Dec., p. 649.

Medical Devices Legislation
FDA—Social Trend and Regulatory Reform. Nov., p. 605.
Recent Developments Under FOIA and FACA Directly Affecting the Pharamceutical Industry. Sept., p. 507.

Microbiological Standards
The Role of Microbiology in the Integrity of Foods. Jan., p. 17.

Milardo, Edward—Quality Assurance Guidelines—The Industry's Viewpoint. Feb., p. 105.

Miller, Michael J.—The Cost Effectiveness of Medical Device Standards. Feb., p. 81.

Mongiardo, James F.—A Response to New Approaches to Be Used in the Regulation of Animal Drugs. Jan., p. 59.

Monographs
Evolving Approaches to the Regulation of Prescription Drugs. Sept., p. 521.
The Role of the Compendia in Establishing Drug Standards. May, p. 276.

Morey, Richard S.—Handling FDA Injunction Actions. June, p. 366.

The *Morgan* Decision
Section 305 Hearings—Defense Considerations. July, p. 386.

Myers, Maven J. and Fink, Joseph L.—Legal Considerations in Establishing Third and Fourth Classes of Drug Products. Jan., p. 4.

N

NAS-NRC GRAS List Survey (Phase III)—Incentives for Further Industry Cooperation and Participation. Mar., p. 132.

National Cancer Institute
An Approach to Toxicological Evaluation. Dec., p. 640.

National Canners Association
FDA With a Capital "L". Dec., p. 649.

National Center for Toxicological Research
An Approach to Toxicological Evaluation. Dec., p. 640.

Nesheim, Robert O.—Management of Scientific Resources. July, p. 413.

The Network of Consumer Information. Dec., p. 664.

The New Age of FDA Rule-Making. July, p. 396.

New Animal Drug Applications
Bioequivalence/Bioavailability—The Basic Legal and Philosophical Issues. Jan., p. 46.
Bioequivalence/Bioavailability—The FDA's Plans. Jan., p. 32.
Bioequivalence/Bioavailability—A Manufacturer's View. Jan., p. 39.
Drug Law—Regulatory Developments. Apr., p. 211.
Evolving Approaches to the Regulation of Prescription Drugs. Sept., p. 521.
How to Comply with the New Medical Device Law. June, p. 312.
The Medical Device Amendments of 1976—Major Features and Comparisons. Aug., p. 424.
New Regulatory Concepts in Rx Labeling for Patients. Sept., p. 531.
Recent Developments Under FOIA and FACA Directly Affecting the Pharmaceutical Industry. Sept., p. 507.
A Response to New Approaches to Be Used in the Regulation of Animal Drugs. Jan., p. 59.
The Role of the Compendia in Establishing Drug Standards. May, p. 276.

New Drug Regulations
Current Topics in Canadian Drug Regulatory Affairs. Jan., p. 11.

New Regulatory Concepts in Rx Labeling for Patients. Sept., p. 531.

1966 Fair Packaging and Labeling Act
Cosmetic Law—Pending Litigation. Apr., p. 198.

Not Invented Here Syndrome
Management of Scientific Resources. July, p. 413.

Notice of Hearing
Section 305 Hearings—Defense Considerations. July, p. 386.

Nutrients
Food Regulations: Quo Vadis? Apr., p. 188.

Nutrition Regulations in Product Development. Apr., p. 232.

Nutrition Labeling
Consumer Interests—Do We Get the Foods We Want? Dec., p. 656.
Management of Scientific Resources. July, p. 413.

Nutritional Standards
Food Regulation: Quo Vadis? Apr., p. 188.

O

Old Drug Monograph Approach
Drug Law—Regulatory Developments. Apr., p. 211.

O'Keefe, Daniel F. and Isley, C. Willard *Dotterweich* Revisited—Criminal Liability Under the Federal Food, Drug and Cosmetic Act. Feb., p. 69.

Oral Contraceptives
FDA With a Capital "L". Dec., p. 649.

Oser, Bernard L.—Are Food Additives Overregulated? Nov., p. 627.

Over-the-Counter Drug Enforcement
Enforcement Trends Under the Federal Food, Drug and Cosmetic Act —A View from Outside. June, p. 338.

Over-the-Counter Drug Monographs
Changing Regulatory Patterns: New Device Legislation. Apr., p. 204.

Over-the-Counter Drugs
Bioequivalence/Bioavailability—The Basic Legal and Philosophical Issues. Jan., p. 46.
The FDA's OTC Review—The Light at the End of the Tunnel. Mar., p. 141.
The FTC's Proposed Rule on OTC Drug Advertising. Mar., p. 147.
Legal Considerations in Establishing Third and Fourth Classes of Drug Products. Jan., p. 4.
The Medical Device Amendments of 1976—Major Features and Comparisons. Aug., p. 424.
New Regulatory Concepts in Rx Labeling for Patients. Sept., p. 531.

An Overview of Recent Regulatory Developments—The Case for Evidentiary Hearings. Mar., p. 159.

An Overview of Recent Regulatory Developments—Veterinary Medicine. Mar., p. 153.

P

The *Park* Case in Perspective. Mar., p. 137.

The *Park* Decision
Cosmetic Quality Assurance—Alias Cosmetic Good Manufacturing Practices. Mar., p. 167.
Dotterweich Revisited—Criminal Liability Under the Federal Food, Drug and Cosmetic Act. Feb., p. 69.
Enforcement Trends Under the Federal Food, Drug and Cosmetic Act—A View from Outside. June, p. 338.
Section 305 Hearings and Criminal Prosecutions. July, p. 376.
Section 305 Hearings—Defense Considerations. July, p. 386.
A Violation of the Federal Food, Drug and Cosmetic Act—A Crime in Search of a Criminal. Nov., p. 616.

Patient Package Inserts
The Network of Consumer Information. Dec., p. 664.

Pendergast, William R.—Evolving Approaches to the Regulation of Prescription Drugs. Sept., p. 521.

Performance Standards
The Cost of Effectiveness of Medical Device Standards. Feb., p. 81.

Pfeifer, Eugene M.—Section 305 Hearing and Criminal Prosecutions. July, p. 376.

Phenametrazine
Legal Developments Relating to Controlled Drugs. Aug., p. 465.

The Philosophy of Enforcement. June, p. 324.

Pietrangelo, Michael A.—Cosmetic Quality Assurance—Alias Cosmetic Good Manufacturing Practices. Mar., p. 167.

Pinco, Robert G.—The FDA's OTC Review—The Light at the End of the Tunnel. Mar., p. 141.

Pines, Wayne L.—Regulatory Letter, Publicity and Recalls. June, p. 352.

Plea Bargaining
The Role of the Department of Justice in Enforcing the Federal Food, Drug and Cosmetic Act. June, p. 333.

Premarket Approval
How to Comply with the New Medical Device Law. June, p. 312.
The Medical Device Amendments of 1976—Major Features and Comparisons. Aug., p. 424.

Premarket Approval Application
Well-Controlled Investigations Under the Medical Device Amendments of 1976. Sept., p. 485.

Premarket Product Safety Data
FDA With a Capital "L". Dec., p. 649.

Prescription Drugs
Evolving Approaches to the Regulation of Prescription Drugs. Sept., p. 521.
FDA With a Capital "L". Dec., p. 649.

Procedural Regulations
Balanced Government Regulation of Consumer Products. Nov., p. 592.

Product Development Protocol
How to Comply with the New Medical Device Law. June, p. 312.
Well-Controlled Investigations Under the Medical Device Amendments of 1976. Sept., p. 485.

Product Liability—1975. Mar., p. 175.

Product Positioning
Regulatory Survival Kit. Apr., p. 241.

Product Recall. July, p. 383.

Protein Efficiency Ratio
Food Regulations: Quo Vadis? Apr., p. 188.
Nutrition Regulations in Product Development. Apr., p. 232.

Publicity
Recalls, Regulatory Letter and Publicity—Quasi-Statutory Remedies. June, p. 360.

Q

Quality Assurance Guidelines—The Industry's Viewpoint. Feb., p. 105.

Quality Assurance Procedures for the Cosmetics Industry—The FDA's Viewpoint. Feb., p. 101.

R

Raubicheck, Charles J. and Weigel, William F.—How to Comply With the New Medical Device Law. June, p. 312.

Recall Procedures
Product Recall. July, p. 383.

Recalls
The Philosophy of Enforcement. June, p. 324.
Product Recall. July, p. 383.
Recalls, Regulatory Letter and Publicity—Quasi-Statutory Remedies. June, p. 360.
Regulatory Letter, Publicity and Recalls. June, p. 352.

Recalls, Regulatory Letters and Publicity—Quasi-Statutory Remedies. June, p. 360.

Recent Developments Under FOIA and FACA Directly Affecting the Pharmaceutical Industry. Sept., p. 507.

Recommended Daily Allowance
Food Regulation: Quo Vadis? Apr., p. 188.
Nutrition Regulations in Product Development. Apr., p. 232.
Special Problems in Advertising. May, p. 252.

Red No. 2
Alternatives to Peril. Sept., p. 497.
An Approach to Toxicological Evaluation. Dec., p. 640.
Are Food Additives Overregulated? Nov., p. 627.
Food Regulation: Quo Vadis? Apr., p. 188.
Toxicology—The Exact Use of an Inexact Science. Aug., p. 455.

Reglamento Alimentario
The Food Law of Argentina. Oct., p. 545.

Regulatory Agencies
Balanced Government Regulation of Consumer Products. Nov., p. 592.
FDA—Social Trend and Regulatory Reform. Nov., p. 605.

Regulatory Aspects of Food Additives—Yesterday, Today and Tomorrow. May, p. 264.

Regulatory Letter, Publicity and Recalls. June, p. 352.

Regulatory Letters
Enforcement Trends Under the Federal Food, Drug and Cosmetic Act—A View from Outside. June, p. 338.

Recalls, Regulatory Letters and Publicity—Quasi-Statutory Remedies. June, p. 360.
Regulatory Letters, Publicity and Recalls. June, p. 352.
Regulatory Survival Kit. Apr., p. 241.
Reiss, Elaine S.—Special Problems in Advertising. May, p. 252.

Research Responsibility
Regulatory Survival Kit. Apr., p. 241.
A Response to New Approaches to Be Used in the Regulation of Animal Drugs. Jan., p. 59.
Review of the 1970 NAS GRAS Pilot Survey (Phase I) and the 1971 NAS Comprehensive Survey (Phase II). Jan., p. 26.
Roberts, Howard R.—Food Additives—A Study in the Evolution of Safety. July, p. 404.
Rodwin, Roger M.
Drug Law—Regulatory Developments. Apr., p. 211.
A Violation of the Federal Food, Drug and Cosmetic Act—A Crime in Search of a Criminal. Nov., p. 616.
The Role of the Compendia in Establishing Drug Standards. May, p. 276.
The Role of the Department of Justice in Enforcing the Federal Food, Drug and Cosmetic Act. June, p. 333.
The Role of Microbiology in the Integrity of Foods. Jan., p. 17.

Rule-Making Authority
The New Age of FDA Rule-Making. July, p. 393.

S

Salmonella
Status of the FDA's Program on the Use of Antibiotics in Animal Feeds. Jan., p. 54.

Sanitary Code
The Food Law of Argentina. Oct., p. 545.
Sayer, Murray D.—Food Regulation: Quo Vadis? Apr., p. 188.
Schmidt, Alexander M.—FDA Social Trend and Regulatory Reform. Nov., p. 605.

Section 305 Hearings
Section 305 Hearings and Criminal Prosecutions. July, p. 376.
Section 305 Hearings—Defense Considerations. July, p. 386.
Section 305 Hearings and Criminal Prosecutions. July, p. 376.
Section 305 Hearings—Defense Considerations. July, p. 386.

Sensitivity of Method Regulation
FDA With a Capital "L". Dec., p. 649.
Special Problems in Advertising. May, p. 252.
Spencer, Robert L.—Bioequivalence/Bioavailability—The FDA's Plans. Jan., p. 32.
Sperber, Philip—Well-Controlled Investigations Under the Medical Device Amendments of 1976. Sept., p. 485.

Section 701 (a) Regulations
The New Age of FDA Rule-Making. July, p. 393.

Standard-Making Procedures
Changing Regulatory Patterns: New Device Legislation. Apr., p. 204.

The *Starr* Decision
A Violation of the Federal Food, Drug and Cosmetic Act—A Crime in Search of a Criminal. Nov., p. 616.
Status of the FDA's Program on the Use of Antibiotics in Animal Feeds. Jan., p. 54.
Status Report on Cosmetic Ingredient Labeling. Feb., p. 121.
Sunshine, Gary A.—Regulatory Aspects of Food Additives—Yesterday, Today and Tomorrow. May, p. 264.
Swire, James B.—Changing Regulatory Patterns: New Device Legislation. Apr., p. 204.

T

Temporary Restraining Order
Handling FDA Injunction Actions. June, p. 366.

Toxicological Testing
An Approach to Toxicological Evaluation. Dec., p. 640.
Toxicology—The Exact Use of an Inexact Science. Aug., p. 455.

Trade Secrets
Cosmetic Ingredient Labeling Requirements. Feb., p. 115.

U

The Use of Regulations to Enforce Statutory Quality Assurance Requirements. Feb., p. 96.

V

Veterinary Medicine
An Overview of Recent Regulatory Developments—Veterinary Medicine. Mar., p. 153.
A Response to New Approaches to Be Used in the Regulation of Animal Drugs. Jan., p. 59.
A Violation of the Federal Food, Drug and Cosmetic Act—A Crime in Search of a Criminal. Nov., p. 616.

W

Walden, John T.—FDA With a Capital "L". Dec., p. 649.
Wanted—Plain Talk About Additives. Aug., p. 448.
Weigel, William F.—New Regulatory Concepts in Rx Labeling for Patients. Sept., p. 531.
Weigel, William F. and Raubicheck, Charles J.—How to Comply With the New Medical Device Law. June, p. 312.
Well-Controlled Investigations and Medical Devices. Feb., p. 86.
Well-Controlled Investigations Under the Medical Device Amendments of 1976. Sept., p. 485.
Wenninger, John A.—Quality Assurance Procedures for the Cosmetics Industry—The FDA's Viewpoint. Feb., p. 101.

White House Conference of 1969
Food Regulation: Quo Vadis? Apr., p. 188.
White, Philip L.—Alternatives to Peril. Sept., p. 497.
Whitehorn, William V.—Consumer Interests—Do We Get the Foods We Want? Dec., p. 656.

The *Wiesenfeld* Decision
A Violation of the Federal Food, Drug and Cosmetic Act—A Crime in Search of a Criminal. Nov., p. 616.

World Health Organization
Food Law—International. Apr., p. 218.

Y

Yingling, Gary L.—An Overview of Recent Regulatory Developments—Veterinary Medicine, Mar., p. 153.
Young, Anthony L.—Recent Developments Under FOIA and FACA Directly Affecting the Pharmaceutical Industry. Sept., p. 507.

Z

Zimmerman, Julius G.—Food Law—International. Apr., p. 218.
Zimmerman, Julius G. and Alfaro, Julio E.—The Food Law of Argentina. Oct., p. 545.